CLAIMS

What is claimed is:

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- 1. A sterilized polymeric material for use in a body of a mammal wherein said polymeric material is sterilized by irradiation at a temperature below 25 °C.
 - 2. The sterilized polymeric material of claim 1 which further comprises a therapeutically active agent.
- 3. The sterilized polymeric material of claim 1 wherein said temperature is at or below about 5 °C.
 - 4. The sterilized polymeric material of claim 2 which comprises polymeric microspheres, microparticles, microcapsules, or implants.
 - 5. The sterilized polymeric material of claim 2 which comprises polymeric microspheres, microparticles, or microcapsules.
- 15 6. The sterilized polymeric material of claim 5 which comprises polymeric microparticles.
 - 7. The sterilized polymeric material of claim 5 which comprises polylactide-co-glycolide or polylactic acid.
 - 8. The sterilized polymeric material of claim 5 which comprises polylactide-co-glycolide.
 - 9. The sterilized polymeric material of claim 5 wherein said temperature is below about 15 °C.
 - 10. The sterilized polymeric material of claim 5 wherein said temperature is below about 10 °C.
 - 11. The sterilized polymeric material of claim 5 wherein said composition temperature is at or below about 5 °C.
 - 12. The sterilized polymeric material of claim 5 which is sterilized by gamma irradiation at a dose of about 1.5 to about 4.0 mRad.
- 13. The sterilized polymeric material of claim 5 wherein said
 therapeutically active agent comprises a retinoid, a prostaglandin, a tyrosine kinase inhibitor, a glucocorticoid, an androgenic steroid, an estrogenic steroid, a

non-estrogenic steroid, an intracellular adhesion molecule inhibitor or an alpha-2-adrenergic agonist.

- 14. The sterilized polymeric material of claim 5 wherein said therapeutically active agent comprises a retinoid.
- 15. The sterilized polymeric material of claim 5 wherein said therapeutically active agent comprises tazarotene.

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- 16. A method of sustained delivery of a therapeutically active agent to a mammal comprising administering a sterilized polymeric material comprising said therapeutically active agent to said mammal, wherein the polymeric material is sterilized by irradiation at a temperature below 25 °C.
- 17. The method of claim 16 wherein the sterilization by irradiation comprises gamma irradiation.
- 18. The method of claim 17 wherein said temperature is below about 15 °C.
- 15 19. The method of claim 17 wherein said temperature is below about 10 °C.
 - 20. The method of claim 17 wherein said temperature is below about 5 °C.
- 21. The method of claim 17 wherein said temperature is from -25°C to 5 °C.
 - 22. A method of sterilizing a polymeric material for use in a body of a mammal comprising irradiating said polymeric material at a temperature below 25 °C.
- 23. The method of claim 22 wherein the polymeric material further comprises a therapeutically active agent.
 - 24. The method of claim 22 wherein said temperature is below about 15 °C.
 - 25. The method of claim 22 wherein said temperature is below about 10 °C.
- The method of claim 22 wherein said temperature is below about 5 °C.

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- 27. A composition comprising sterilized polymeric microparticles and a therapeutically active agent for use in a body of a mammal wherein said polymeric material is sterilized by irradiation with external cooling of said polymeric material during sterilization.
- 28. The composition of claim 27 wherein said composition is suitable for sustained delivery of said therapeutically active agent.

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- 29. The composition of claim 27 wherein the temperature of said polymeric material at the end of the sterilization process is about 10 °C to about 50 °C lower than said temperature would be in the absence of external cooling.
- 30. The composition of claim 27 wherein the temperature of said polymeric material at the end of the sterilization process is about 20 °C to about 50 °C lower than said temperature would be in the absence of external cooling.
- 31. The composition of claim 27 wherein the temperature of said polymeric material at the end of the sterilization process is about 50 °C or more lower than said temperature would be in the absence of external cooling.
- 32. A method of sterilizing a polymeric material for use in a body of a mammal comprising irradiating said polymeric material with external cooling of the polymeric material.
- 33. The method of claim 32 wherein the temperature of said polymeric material at the end of the sterilization process is about 10 °C to about 50 °C lower than said temperature would be in the absence of external cooling.
- 34. The method of claim 32 wherein the temperature of said polymeric material at the end of the sterilization process is about 20 °C to about 50 °C lower than said temperature would be in the absence of external cooling.
- 35. The method of claim 32 wherein the temperature of said polymeric material at the end of the sterilization process is about 50 °C or more lower than said temperature would be in the absence of external cooling.
- 36. The method of claim 16 wherein the polymeric material comprises polylactide-co-glycolide or polylactic acid.
- 37. The method of claim 16 wherein the polymeric material comprises polylactide-co-glycolide.

- 38. The composition of claim 27 wherein the polymeric material comprises polylactide-co-glycolide or polylactic acid.
- 39. The composition of claim 27 wherein the polymeric material comprises polylactide-co-glycolide.